



Complete Summary

GUIDELINE TITLE

2002 national guideline for the management of bacterial vaginosis.

BIBLIOGRAPHIC SOURCE(S)

Association for Genitourinary Medicine (AGUM), Medical Society for the Study of Venereal Disease (MSSVD). 2002 national guideline for the management of bacterial vaginosis. London: Association for Genitourinary Medicine (AGUM), Medical Society for the Study of Venereal Disease (MSSVD); 2002. Various p. [27 references]

COMPLETE SUMMARY CONTENT

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis

RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Bacterial vaginosis

GUIDELINE CATEGORY

Diagnosis

Evaluation

Management

Treatment

CLINICAL SPECIALTY

Infectious Diseases

Obstetrics and Gynecology

Urology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To present a national guideline for the management of bacterial vaginosis (BV)

TARGET POPULATION

Women in the United Kingdom with bacterial vaginosis (BV)

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

1. Evaluation of vaginal discharge using the Amsel criteria
2. Microscopic assessment of a gram stained vaginal smear, with the Hay/Ison or Nugent or criteria

Treatment/Management

1. General advice to patients
2. Metronidazole
3. Intravaginal metronidazole gel or intravaginal clindamycin cream or clindamycin
4. Sexual partner management
5. Follow-up

MAJOR OUTCOMES CONSIDERED

Cure rate

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developers performed a Medline search using the terms "bacterial vaginosis" and "treatment" to identify treatment trials and reviews or meta-analyses. The 1994 and 1995-2000 databases were searched. Previous guidelines were sought, and the 1998 USA guidelines reviewed. The Cochrane Library databases were searched using the term "bacterial vaginosis".

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence:

I a

- Evidence obtained from meta-analysis of randomised controlled trials

I b

- Evidence obtained from at least one randomised controlled trial

II a

- Evidence obtained from at least one well designed controlled study without randomisation

II b

- Evidence obtained from at least one other type of well designed quasi-experimental study

III

- Evidence obtained from well designed non-experimental descriptive studies such as comparative studies, correlation studies, and case control studies

IV

- Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The revision process commenced with authors being invited to modify and update their 1999 guidelines. These revised versions were posted on the website for a 3 month period and comments invited. The Clinical Effectiveness Group and the authors concerned considered all suggestions and agreed on any modifications to be made.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grading of Recommendations:

A (Evidence Levels Ia, Ib)

- Requires at least one randomised controlled trial as part of the body of literature of overall good quality and consistency addressing the specific recommendation.

B (Evidence Levels IIa, IIb, III)

- Requires availability of well conducted clinical studies but no randomised clinical trials on the topic of recommendation.

C (Evidence Level IV)

- Requires evidence from expert committee reports or opinions and/or clinical experience of respected authorities.
- Indicates absence of directly applicable studies of good quality.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The initial versions of the guidelines were sent for review to the following:

- Clinical Effectiveness Group (CEG) members
- Chairs of UK Regional GU Medicine Audit Committees who had responded to an invitation to comment on them
- Chair of the Genitourinary Nurses Association (GUNA)
- President of the Society of Health Advisers in Sexually Transmitted Diseases (SHASTD)

- Clinical Effectiveness Committee of the Faculty of Family Planning and Reproductive Health Care (FFP)

Comments were relayed to the authors and attempts made to reach a consensus on points of contention with ultimate editorial control resting with the Clinical Effectiveness Group. Finally, all the guidelines were ratified by the councils of the two parent societies.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Levels of evidence (I-IV) and grades of recommendation (A-C) are defined at the end of the "Major Recommendations" field.

Diagnosis

In clinical practice bacterial vaginosis (BV) is diagnosed using the Amsel criteria. (Amsel et al., 1983) At least three of the four criteria are present for the diagnosis to be confirmed.

1. Thin, white, homogeneous discharge
2. Clue cells on microscopy
3. pH of vaginal fluid >4.5
4. Release of a fishy odor on adding alkali (10% KOH).

An alternative is to use a Gram stained vaginal smear, with the Hay/Ison criteria or the Nugent criteria. The Hay/Ison criteria are defined as follows:

- Grade 1 (Normal): Lactobacillus morphotypes predominate.
- Grade 2 (Intermediate): Mixed flora with some Lactobacilli present, but Gardnerella or Mobiluncus morphotypes also present.
- Grade 3 (Bacterial Vaginosis): Predominantly Gardnerella and/or Mobiluncus morphotypes. Few or absent Lactobacilli. (Hay et al., 1994)

The Nugent score is derived from estimating the relative proportions of bacterial morphotypes to give a score between 0 and 10. A score of <4 is normal, 4 to 6 is intermediate, and >6 is bacterial vaginosis. (Nugent, Krohn & Hillier, 1991)

Isolation of Gardnerella vaginalis cannot be used to diagnose bacterial vaginosis because it can be cultured from the vagina of more than 50% normal women (Evidence Level IIa). In research studies a high concentration of Gardnerella vaginalis is associated with the presence of bacterial vaginosis (Evidence Level IIa). (McDonald et al., 1997)

Management

General advice

Patients should be advised to avoid vaginal douching, use of shower gel, and use of antiseptic agents or shampoo in the bath (Grade of Recommendation C).

Treatment

Treatment is indicated for:

- Symptomatic women (Grade of Recommendation A)
- Women undergoing some surgical procedures (Grade of Recommendation A)
- Some pregnant women (Grade of Recommendation A)

Women who do not volunteer symptoms may elect to take treatment if offered. They may report a beneficial change in their discharge following treatment.

Recommended regimens

- Metronidazole 400 to 500 mg twice daily for 5 to 7 days (Grade of Recommendation A)

or

- Metronidazole 2 g immediately (Grade of Recommendation A).

Alternative regimens

- Intravaginal metronidazole gel (0.75%) once daily for 5 days (Grade of Recommendation A)

or

- Intravaginal clindamycin cream (2%) once daily for 7 days (Grade of Recommendation A)

or

- Clindamycin 300 mg twice daily for 7 days (Grade of Recommendation A).

Rationale

All these treatments have been shown to achieve cure rates of 70 to 80% after 4 weeks in controlled trials using placebo or comparison with oral metronidazole. (Hay, 1998; Centers for Disease Control and Prevention, 1998; Management of Bacterial Vaginosis, 1998; Larsson, 1992; Lugo-Miro, Green, & Mazur, 1992; Hillier et al., 1993) Oral metronidazole treatment is established, usually well tolerated, and inexpensive (Ia). Dosage and duration used in trials have varied from 400 mg twice daily for 5 days to 500 mg twice daily for 7 days. The 2 g immediate dose may be slightly less effective at 4 week follow up (Ib).

Intravaginal metronidazole gel and clindamycin cream have similar efficacy (Ib), but the latter is more expensive. Theoretically, metronidazole has an advantage

because it is less active against lactobacilli than clindamycin. Conversely, clindamycin is more active than metronidazole against most of the bacteria associated with bacterial vaginosis.

Oral clindamycin has only been evaluated in one study with short term follow up, and in pregnant women (Evidence Levels Ib, IIa). It is more expensive than metronidazole.

Caution

With metronidazole treatment alcohol should be avoided because of the possibility of a disulfiram-like action. There are no data on the risks from consuming alcohol with intravaginal metronidazole gel, but it is not recommended at present. Clindamycin cream can weaken condoms, which should not be used during such treatment. Pseudomembranous colitis has been reported with both oral clindamycin and clindamycin cream. (Trexler, Fraser, & Jones, 1997)

Allergy

Allergy to metronidazole is uncommon. Use 2% clindamycin cream for metronidazole allergic women.

Pregnancy and breast feeding

Meta-analyses have concluded that there is no evidence of teratogenicity from the use of metronidazole in women during the first trimester of pregnancy (Burtin et al., 1995; Caro-Paton et al., 1997; Czeizel & Rockenbauer, 1998) (Evidence Level Ia).

The results of clinical trials investigating the value of screening for and treating bacterial vaginosis in pregnancy have been conflicting. It is therefore difficult to make firm recommendations. In summary, three randomised controlled trials have shown a reduction in the incidence of preterm birth following screening for and treatment of bacterial vaginosis in women with a history of prior idiopathic preterm birth or second trimester loss. However, this was based on a subgroup analysis in two studies, (McDonald et al., 1997; Hauth et al., 1995) and all three studies used different treatments: metronidazole 500 mg twice daily for 7 days; (Morales, Schorr, & Albritton, 1994) metronidazole 400 mg twice daily for 2 days repeated after 4 weeks if indicated; (McDonald et al., 1997) and a combination of metronidazole 250 mg and erythromycin 333 mg both three times daily for 7 days. (Hauth et al., 1995)

The largest multi-centre randomised controlled trial randomized 1953 asymptomatic women with bacterial vaginosis to receive 2 grams metronidazole or placebo, taken under supervision in the clinic, repeated at home 2 days later. (Carey et al., 2000) The course was repeated 4 weeks later. There was no difference in gestational age at delivery between the two groups, or in the subgroup of women with a prior preterm birth. Possible limitations of this study include the relatively late gestational age at which treatment was administered (mostly 20 to 24 weeks gestation), the short course of metronidazole

administered, and the high number of women screened positive for bacterial vaginosis who were not randomized.

One further study has shown a benefit from treatment with oral clindamycin 300 mg twice daily for 7 days. (McGregor et al., 1995) However, a cohort design was used rather than randomization, which limits the value of the study for making treatment recommendations (IIa). The use of clindamycin cream to treat bacterial vaginosis in the second trimester of pregnancy has not produced a reduction in preterm birth in two small studies (McGregor et al., 1994; Joesoef et al., 1995) (Evidence Level Ib).

The results of further randomised controlled trials of screening and treating all pregnant women are awaited, but there are insufficient data to make such a recommendation at present. In conclusion, symptomatic pregnant women should be treated in the usual way (Grade of Recommendation B). Asymptomatic pregnant women with a history of 'idiopathic' preterm birth or second trimester loss may be screened and treated with oral metronidazole 400 mg. twice daily for 7 days, but current evidence does not support routine screening for bacterial vaginosis.

Metronidazole enters breast milk and may affect its taste. The manufacturers recommend avoiding high doses if breast feeding. Small amounts of clindamycin enter breast milk. It is prudent therefore to use an intravaginal treatment for lactating women (Grade of Recommendation C).

Termination of pregnancy (TOP)

One study has demonstrated a reduction in post-termination of pregnancy infection by treating bacterial vaginosis with oral metronidazole before termination (Larsson et al., 1992) (Evidence Level Ib). Another has demonstrated a reduction in infective complications following the use of clindamycin cream (Larsson et al., 2000) (Evidence Level Ib). There are no data on the effectiveness of treatment administered at the time of termination of pregnancy. These two studies support screening for and treating bacterial vaginosis with either metronidazole or clindamycin cream, to reduce the incidence of subsequent endometritis and pelvic inflammatory disease (PID).

Sexual partners

No reduction in relapse rate was reported from two studies in which male partners of women with bacterial vaginosis were treated with metronidazole, one study of tinidazole, and one of clindamycin (Larsson, 1992; Colli, Landoni, & Parazzini, 1997) (Evidence Level Ib). Routine screening and treatment of male partners are therefore not indicated. One small study reported a high incidence of bacterial vaginosis in female partners of lesbian women with bacterial vaginosis (Berger et al., 1995) (Evidence Level III). No study has investigated the value of treating partners of lesbian women simultaneously.

Follow up

A test of cure is not required if symptoms resolve. If treatment is prescribed in pregnancy to reduce the risk of preterm birth, a repeat test should be made after 1 month and further treatment offered if the bacterial vaginosis has recurred.

Recurrent bacterial vaginosis

There are few published studies evaluating the optimal approach to women with frequent recurrences of bacterial vaginosis. Small studies of live yogurt or *Lactobacillus acidophilus* have not demonstrated benefit (Larsson, 1992) (Evidence Level IIa).

Definitions:

Levels of Evidence:

I a

- Evidence obtained from meta-analysis of randomised controlled trials

I b

- Evidence obtained from at least one randomised controlled trial

II a

- Evidence obtained from at least one well designed controlled study without randomisation

II b

- Evidence obtained from at least one other type of well designed quasi-experimental study

III

- Evidence obtained from well designed non-experimental descriptive studies such as comparative studies, correlation studies, and case control studies

IV

- Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

Grading of Recommendations:

A (Evidence Levels I a, I b)

- Requires at least one randomised controlled trial as part of the body of literature of overall good quality and consistency addressing the specific recommendation.

B (Evidence Levels IIa, IIb, III)

- Requires availability of well conducted clinical studies but no randomised clinical trials on the topic of recommendation.

C (Evidence Level IV)

- Requires evidence from expert committee reports or opinions and/or clinical experience of respected authorities.
- Indicates absence of directly applicable studies of good quality.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

[References open in a new window](#)

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is graded and identified for select recommendations (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

The recommended and alternative treatments have been shown to achieve cure rates of 70% to 80% after 4 weeks in controlled trials using placebo or comparison with oral metronidazole.

POTENTIAL HARMS

With metronidazole treatment alcohol should be avoided because of the possibility of a disulfiram-like action. There are no data on the risks from consuming alcohol with intravaginal metronidazole gel, but it is not recommended at present. Clindamycin cream can weaken condoms, which should not be used during such treatment. Pseudomembranous colitis has been reported with both oral clindamycin and clindamycin cream.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The Clinical Effectiveness Group reminds the reader that guidelines in themselves are of no use unless they are implemented systematically. The following auditable outcome measures are provided:

- Diagnosis of bacterial vaginosis (BV) in clinical practice. Compare routine diagnosis with stored vaginal smears examined by Gram stain.
- Screening and treatment of women undergoing termination of pregnancy. This should also include screening for Chlamydia trachomatis.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Association for Genitourinary Medicine (AGUM), Medical Society for the Study of Venereal Disease (MSSVD). 2002 national guideline for the management of bacterial vaginosis. London: Association for Genitourinary Medicine (AGUM), Medical Society for the Study of Venereal Disease (MSSVD); 2002. Various p. [27 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1999 Aug (revised 2002)

GUIDELINE DEVELOPER(S)

British Association of Sexual Health and HIV - Medical Specialty Society

SOURCE(S) OF FUNDING

Not stated

GUIDELINE COMMITTEE

Clinical Effectiveness Group (CEG)

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Author: Phillip Hay

Clinical Effectiveness Group (CEG) Members: Keith Radcliffe (Chairman); Imtyaz Ahmed-Jushuf; Jan Welch; Mark FitzGerald; Janet Wilson

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Phillip Hay has worked as a consultant and investigator in trials for Upjohn and Pharmacia (2% clindamycin cream) and 3M Pharmaceuticals (0.75% metronidazole gel).

GUIDELINE STATUS

This is the current release of the guideline. This guideline updates a previously released version.

An update is not in progress at this time.

GUIDELINE AVAILABILITY

Electronic copies: Available in HTML format from the [Association for Genitourinary Medicine \(AGUM\) Web site](#). Also available in Portable Document Format (PDF) from the [Medical Society for the Study of Venereal Diseases \(MSSVD\) Web site](#).

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- UK national guidelines on sexually transmitted infections and closely related conditions. Introduction. Sex Transm Infect 1999 Aug; 75(Suppl 1): S2-3.

Electronic copies: Available in Portable Document Format (PDF) from the [Medical Society for the Study of Venereal Diseases \(MSSVD\) Web site](#).

The following is also available:

- Revised UK national guidelines on sexually transmitted infections and closely related conditions 2002. Sex Transm Infect 2002; 78: 81-2

Print copies: For further information, please contact the journal publisher, [BMJ Publishing Group](#).

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on June 15, 2000. The information was verified by the guideline developer on October 13, 2000. This summary was updated by ECRI on June 24, 2002.

COPYRIGHT STATEMENT

This NGC summary is based on the original guideline, which is subject to the guideline developers and/or BMJ Publishing Group's copyright restrictions. Reproduction and use of this guideline is permitted provided that (a) the original content is not changed or edited; and, (b) any content derived from the original guideline is acknowledged as that of the author(s) and responsible organizations.

Readers wishing to download and reproduce material for purposes other than personal study or education should contact BMJPG to seek permission first. Contact: BMJ Publishing Group, BMA House, Tavistock Square, WC1H 9JR, UK.

© 1998-2004 National Guideline Clearinghouse

Date Modified: 11/8/2004

